K113703

JUN - 5 2012

510(k) SUMMARY

Submitter Information:

Date Prepared:	May 31, 2012
Name:	Bausch & Lomb Incorporated
Address:	1400 North Goodman Street Rochester, NY 14609
Contact Person:	Barbara Klube-Falso Specialist, Global Regulatory Affairs
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Device Information:

Trade Name: Bausch + Lomb nesofilcon A contact lens

Common Name: Soft daily disposable contact lens

Device Classification: Class II (21 CFR 886.5925)

Predicate Device:

Bausch + Lomb nesofilcon A contact lens is substantially equivalent to the following predicate device:

Bausch + Lomb SofLens® Daily Disposable (hilafilcon B) Visibility Tinted Contact Lens cleared in K061157 on June 22, 2006.

Device Description:

The Bausch + Lomb contact lens is made from nesofilcon A material, a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone, and is 78% water by weight when immersed in a sterile borate buffered saline with 0.5% poloxamine solution. This packaging solution is currently used with other Bausch + Lomb contact lenses. A UV-absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm. This lens is tinted blue with Reactive Blue Dye 246. The color additive conforms to 21 CFR Part 73.3106.

The Bausch + Lomb nesofilcon A contact lens is to be prescribed for single-use disposable wear.

The physical properties of the lens are:

Refractive index	1.374
Light transmission	99%
Water Content	78%
Specific Gravity	1.039
Oxygen Permeability	42 x 10^{-11}[cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg)@35°C (polarographic method)

The lenses will be manufactured with the following properties:

Diameter	13.5mm to 15.0mm
Center Thickness	0.05mm to 0.75mm
Base Curve	7.8mm to 9.5mm
Power Range	+20.00D to -20.00D

The lenses are packaged in disposable blister packages containing borate buffered saline solution. Blister packages are labeled with lot number, expiration date and applicable lens parameters measurement. Expiration dating is supported by product stability, package integrity, and validation of the sterilization process.

Intended Use:

Bausch + Lomb nesofilcon A contact lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes that exhibit refractive astigmatism up to 2.00 diopters or less, that does not interfere with visual acuity. The lens is to be prescribed in spherical powers ranging from +20.00D to -20.00D.

The nesofilcon A contact lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

Technological Characteristics (comparison to Predicate Device)

The table below shows a side-by-side comparison of the predicate device to the new device:

Property	Predicate Device Bausch + Lomb SofLens® Daily Disposable (hilafilcon B) Visibility Tinted Contact Lens	New Device Bausch + Lomb nesofilcon A contact lens
Intended Use	Indicated for the daily wear correction of refractive ametropia (myopia,hyperopia and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes that exhibit refractive astigmatism up to 2.00 diopters or less, that does not interfere with visual acuity. The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.	Same as predicate
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	Same as predicate
Modality	Daily wear contact lens	Same as predicate
Manufacturing Method	Cast Molded	Same as predicate
Material Group	Group II (high water, no ionic polymers)	Same as predicate
USAN Name	hilafilcon B	nesofilcon A
Water Content	59%	78%
Oxygen Permeability[1] (edge corrected)	22	42
Oxygen Permeability[1] (non-edge corrected)	NA	50
Specific Gravity	1.119	1.039
UV Blocker	NA	Yes

[1]- Oxygen Permeability shown was determined by the polarograhic method:
$\times 10^{-11}[cm^3O_2(STP) \times cm]/(sec \times cm^2 \times mmHg)@35°C$

Summary of Non-Clinical Testing:

The testing performed on the Bausch + Lomb nesofilcon A contact lens demonstrated that the device functions in a safe and effective manner. Performance testing included conformance to predetermined specifications, functional test results verify that the device performs as expected and is equivalent to the predicate without creating additional risk to the user.

In addition, Bausch + Lomb followed the *FDA Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses,* May 1994, the following tests were conducted:

Toxicology / Biocompatibility

In-Vitro Cytotoxicity

Ocular Irritation Study

Systemic Toxicity

Chemistry / Leachables

Physical, Chemical and Spectral Properties

Leachable Monomer and Additives

Summary of Clinical Performance Data

Bausch + Lomb conducted a controlled clinical study, comparing the safety and efficacy of Bausch + Lomb nesofilcon A contact lens to Bausch + Lomb SofLens® Daily Disposable (hilafilcon B) Visibility Tinted Contact Lens. The results of the study support a substantial equivalence determination.

Substantial Equivalence Conclusion:

The cumulative results of laboratory, *in vitro, in vivo* testing as well as the clinical study sponsored by Bausch + Lomb demonstrate that the safety, efficacy and performance of Bausch + Lomb nesofilcon A contact lens are substantially equivalent to Bausch + Lomb SofLens® Daily Disposable (hilafilcon B) Visibility Tinted Contact Lens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bausch + Lomb, Inc.
c/o Ms. Barbara Klube-Falso
Specialist, Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

JUN - 5 2012

Re: K113703
Trade/Device Name: Bausch + Lomb nesofilcon A contact lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: MVN, and LPL
Dated: May 25, 2012
Received: May 29, 2012

Dear Ms. Klube-Falso:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113703

Indications for Use Statement

510(k) Number (if known): K113703

Device Name: Bausch + Lomb nesofilcon A contact lens

nesofilcon A
Bausch + Lomb nesofilcon A contact lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes that exhibit refractive astigmatism up to 2.00 diopters or less, that does not interfere with visual acuity. The lens is to be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Hampton for Krawczyk

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113703